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Vela Diagnostics

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Companion diagnostics for NGS and qPCR

Vela Diagnostics launches first automated diagnostics for NGS and qPCR, and announcescapability for companion diagnostics with pharma partners.

A total IVD solution with standardised automated workflow for more than 30 qPCR and eight NGS testshas been launched by Vela Diagnostics, a fast-growing molecular diagnostics manufacturing company which specialises in end-to-end systems.Of these,more than 25 IVD qPCR tests and four NGS tests will be available by the end of September 2014, subject to local regulatory status.

Established in 2011, with former topRoche executive Michael Tillmann leading a strong management team and more than 100 people in research and development, Vela Diagnostics has achieved avery rapidrollout of its system, testsand analysis software tools in just three years.

It is believed to be the only company to date offering an IVD test based on NGS for oncology and infectious diseases, and will launchfour panels (melanoma, CRC, NSCLC and hepatitis C) in August 2014. A leukaemia panel is planned for Q4/2014.

Dr Bhuwnesh Agrawal, a pharmacologist and toxicologist who is Vela's Chief Medical Officer and Head of Pharma Partnership, says the company was established because significant shortcomings in existing molecular diagnostic solutions had been identified.

"There were very few platforms offering more than three or four tests, so to have a reasonable menu a pathologist would require five systems with all the associated costs of space, inventory and training.Many systems were manual, which raises issues of quality, reliability and potential for error."

A single system with 30 parameters

"With our innovation, you will have 30 parameters in the one system and you can add sequencing to it, so it is a great deal more effective and efficient. We think of it as standardised versatility and believe that it is unique in the industry."

Globally, the company's qPCR tests are available for respiratory infections, gastroenteritis, ISP, oncology, leukaemia, tropical infections, blood borne viruses, microbiology and STD, though local availability depends on regulatory status.A very small sample size of about 5 – 10ng of DNA is required for NGS tests, compared to the 100 – 150ng needed by other systems.

In addition to the key benefits of convenience and efficiency, the system's speed is impressive. Turnaround time for qPCR is less than four hours, while NGS results are achieved in about two days compared to five to seven days with manual systems.

Automated workflows result in tests which are very sensitive, specific, reliable and above all, extremely reproducible. All results are automatically evaluated through the bioinformatics system and fed into the client's lab information system, with Vela's Sentosa® Reporter software considerably reducing pathology time in interpreting results.

While the integrated solution includes hardware, software, bioinformatics, reagents and services tailored to the needs of each customer, Vela has succeeded in avoiding the complexities usually associated with such technological innovation.

"We have simplified everything, and our IVD tests provide the necessary information for clinical decision making, which makes it very useful and convenient as companion diagnostics," Dr Agrawal said.

Key pharma benefits

Convenience and reliability	**Pharma needs-oriented**	**Technical superiority**
• High reproducibility, sensitivity, specificity and automation, low hands-on time. • Excellent performance in QCMD. • TAT <4h for PCR, 2 days for NGS. • Automated bioinformatics.	• Low sample amount required (5-10ng DNA for NGS). • Diagnostic-experienced organisation, strong R&D. • CLIA lab, ISO 13485:2003 certified, QMS in accordance with cGMP. • Fast development times.	• Cutting edge technology (qPCR, NGS). • Full automation. >14 sample types, >60 run files, >25qPCR tests on one system (currently)*. • 5 NGS panels planned for CE-IVD in 2014 with broad, relevant coverage.

*Local availability based on regulatory status

Vela executives have extensive experience in pharma development, and have built an organisational culture that is strongly focused on innovation, rapid decision making and development speed. The company hasrobust diagnostic capabilities and its highly skilled R&D/Q&A team of almost 100 people comprisesabout 50 per cent of its workforce.

"Generally whenmolecular diagnostics companies develop tests, they take about three years. We do it in around six to 12 monthsfor sequencing as well as PCR,"Dr Agrawal said.

"As targeted treatments require specific diagnostic tools, Vela's broad experience as a team on both qPCR and NGS can provide customised solutions, which are specific to the needs of pharma partners."

Vela's global presence comprises offices in the USA, Europe and Asia, R&D sites in Singapore, Malaysia and the USA with a CLIA lab. The company is ISO 13485:2003 certified and has achieved excellent performance in QCMD. Regulatory approvals have been completed in Europe and most other countries, with FDA approvals a high priority.

Despite its relative youth, the company has already attracted the attention and the high interest of large laboratory chains, particularly in Asia.

Vela Diagnosticsis also keen to discuss off-the-shelf and customised testing solutions with pharma companies, including development of companion diagnostics for NGS and qPCR.